

May 24, 1999

DOCKETS MANAGEMENT BRANCH (HFA-305)
FOOD AND DRUG ADMINISTRATION MAY 28 09:09
ROOM 1061
5630 FISHERS LANE
ROCKVILLE, MD 20857-0003

RE: DOCKET NO. 98N-1265

Gentlemen:

We disapprove of the Memorandum of Understanding as published by the FDA on January 21, 1999.

In its present form, the MOU, as well as the Compounding Section 503A of the Modernization Act, severely restricts the rights of the physicians and patients to obtain health care products from the provider of their choice. It also infringes on the rights of compounding pharmacists to serve the public's medical needs. There should be no restrictions on the delivery of compounded medication prescribed for me, regardless of where we live or travel.

The Food and Drug Administration is responsible to oversee the safety of drugs. However, in the case of compounded drugs, there is no safety issue, and no need for further restriction. The MOU as it is now written will unfairly restrict access to compounded drugs which we require for our health and well-being.

We trust that you will take our needs into consideration.

Sincerely,

John and Gervais Crouch

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105 Morningside Drive
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98N-1265

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